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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/695,574	10/28/2003	Denis Barritault	1003-DIV-01	4857

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EXAMINER	
FERNANDEZ, SUSAN EMILY	

ART UNIT	PAPER NUMBER
1651	

MAIL DATE	DELIVERY MODE
03/17/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/695,574	BARRITAULT ET AL.	
	Examiner	Art Unit	
	SUSAN E. FERNANDEZ	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 October 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *65-68* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *65-68* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment and declaration filed October 31, 2007, has been received and entered.

Claims 67 and 68 are new. Claims 1-64 are cancelled.

Claims 65-68 are pending and examined on the merits to the extent they read on the elected subject matter.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 65-68 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the *in vitro* use of RGTA 1112 and 1113 (CM_2DPheS2 and CM_3DTyrS2, shown in Figure 26) for treating **factors involved in fibroses**, does not reasonably provide enablement for treating fibroses with all other AXYZ polymers. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Regarding undue experimentation, *In re Wands*, 8 USPQ2d 1400, at 1404 (Fed. Cir. 1988) states:

> Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in *Ex parte Forman*. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. (Citations omitted).

The rejected claims are drawn to the method of treating fibroses (including fibroses of smooth muscle and mesenchymal tissues) by administering a pharmaceutical composition comprising the AXYZ polymer. The claims are broad enough to encompass an infinite number of polymers, of which experimentation would be required for every single variant to determine their efficacy as antifibrotic agents. For the treatment of fibroses, Z is further limited to phenylalanine and tyrosine, as is shown in Figure 26 (CM_2DPheS2 and CM_3DTyrS2).

Though the specification demonstrates through *in vitro* experiments that the AXYZ polymers CM_2DPheS2 and CM_3DTyrS2 are suitable for the treatment of fibroses, no experiments are described for the testing of all other AXYZ polymers for their efficacy in treating fibroses. The specification does not provide actual guidance or evidence supporting the use of each and every polymer defined by claims 65-68 in treating fibroses.

In sum, a skilled artisan would have expected to have had to engage in an essentially trial and error process, with little guidance from the specification as filed, to determine suitable AXYZ polymers which treat every type of fibrosis. Such a trial and error process clearly constitutes undue experimentation.

Claims 65, 67, and 68 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

First, claim 65 comprises new matter. The recitation of what Z represents at lines 9-12 of claim 65 is considered new matter. Page 22, lines 1-5 indicates that when A is –(O-CH_2-CH_2-CO)-, X is –COOH or –COO^-Na^+, and Y is –CO-CH_2-CHOH-CH_2-SO_3H or –CO-CH_2-CHOH-CH_2-$SO_3^-Na^+$, then Z is –CO-OCH_3-CH(CH_2-CH_3)-CH_3. The specification does not specify in any other instance that in the case where A, X, and Y are defined as above, that the Z is any other compound.

Additionally, claim 67 comprises new matter since the specification does not teach that when Z is phenylalanine or tyrosine, Y is $-SO_3^-$ or $-SO_3H$. Instead, the specification teaches that Y is an $-OSO_3^-$ group (page 34, lines 17-18). Further still, the substitution rate ranges recited for each of x, y, and z are not specifically recited in the specification.

Claim 68 comprises new matter since the specification does not teach that Z can be acetate. Furthermore, the substitution rate ranges recited for each of x, y, and z are not specifically recited in the specification.

Because the specification as filed fails to provide clear support for the new claim language, a new matter rejection is clearly proper.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 67 and 68 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 67 and 68 are rendered indefinite by the recitation "AaXxYyZz." For appropriate formula notation, the recitation should be replaced with "$A_aX_xY_yZ_z$."

Response to Arguments

Applicant's arguments filed October 31, 2007, have been fully considered but they are not persuasive. Applicant asserts that the specification provides sufficient guidance and information to allow one skilled in the art to make and use AXYZ polymers for the treatment of fibroses. While guidance is provided to make the AXYZ polymers, there is undue and extensive amount of experimentation required to verify whether each and every one of these many polymers can successfully treat fibroses. Given that Z may be a fatty acid, amino acid, fatty alcohol, ceramide or *derivatives thereof*, and nucleotide addressing sequences, Z may be any one of various chemical groups, thus there would have been at least near infinite number of polymers defined by the claims. The declaration under 37 CFR 1.132 filed October 31, 2007 is insufficient to overcome the rejection of the claims because the Mangoni study discussed in the declaration deals with the state of the art existing at post-filing, and not the state of the art existing at the filing date of the application. Note that MPEP 2164.05(a) indicates that "The state of the art existing at the filing date of the application is used to determine whether a particular disclosure is enabling as of the filing date." Furthermore, MPEP 2164.05(a) states that "Publications dated after the filing date providing information publicly first disclosed after the filing date generally cannot be used to show what was known at the time of filing."

Moreover, it is noted that the Mangoni study teaches an AXYZ polymer which does not meet the Z monomer limitations recited in claims 65-67. Acetate as the Z monomer does not

meet the requirement that "Z represent at least one functional chemical group, which is different from X and Y, selected from the group consisting of a fatty acid, amino acid, fatty alcohol, ceramide or derivative thereof and nucleotide addressing sequences and which confers supplementary biological or physiochemical properties." Finally, the Denoix study concerning the response of equine tendonitis to OTR4131 is in reference to the prevention of the development of fibrotic tissue, not the treatment of fibroses as required by the instant claims.

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSAN E. FERNANDEZ whose telephone number is (571)272-3444. The examiner can normally be reached on Mon-Fri 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leon B Lankford Jr/
Primary Examiner, Art Unit 1651

Susan E. Fernandez
Examiner
Art Unit 1651

scf